

## REMARKS

In the Office Action, the Examiner required restriction to one of the following inventions under 35 USC § 121:

- I. Claims 1-19, drawn to a method for making an insulin-containing particulate product;
- II. Claims 20-68, drawn to a method for making multi-component particles containing insulin and a biocompatible polymer;
- III. Claims 69-76, drawn to a device.

The Examiner has also made a species restriction and has required election of a single-disclosed species. In particular, the examiner notes that the claims of Group I and Group II inventions are generic to a plurality of species, namely:

- a. species of anti-solvent fluid;
- b. species of a first organic solvent;
- c. species of second organic solvent.

With respect to the Group II invention, the examiner also notes a plurality of species of a biocompatible polymer.

The Group I claims (Claims 1-19) are elected without traverse for examination at this time. Also, Claim 20 is being amended herewith so that Claim 1 is now also generic to Claims 20-48. Claim fees have already been paid for examination of Claims 20-48, and the amendment to Claim 20 is being made solely for the purpose of taking advantage of the claim fees already paid to have additional embodiments presented for examination at this time with the elected invention, and not for any reason related to patentability.

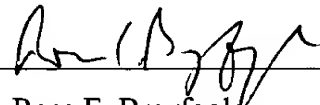
Election of species are also made without traverse. For the anti-solvent fluid, carbon dioxide is elected as the ultimate specie for examination. Claims 1-48 are readable on carbon dioxide as the anti-solvent fluid. For the first organic solvent, DMSO is elected as the ultimate specie for examination. Claims 1-24 and 28-48 are readable on DMSO as the first organic solvent. For the second organic solvent, isopropanol is elected as the ultimate specie for examination. Claims 1-21, 24-27 and 29-48 read on isopropanol as the second organic solvent. Also, Claims 20-48 all require a biocompatible polymer. To the extent necessary, poly(lactic acid) is elected as the ultimate specie of biocompatible polymer for examination. Claims 1-48 are readable on poly(lactic acid) as the biocompatible polymer.

Claim 30 is being amended to correct a typographical error to replace "and" with "an".  
Claim 48 is being amended to correct an erroneous dependency. The amendments to Claims 30 and 48 are not being made for any reason related to patentability.

Also enclosed is a Petition For an Extension of Time Under 37 CFR 1.136(a) and a check in the amount of \$55 for a one-month extension fee under 37 CFR 1.17(a). No other fees are believed to be due with this communication. If any additional fees are due, please debit such fees to deposit account No. 50-1419.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

By: 

Ross E. Breyfogle  
Registration No. 36,759  
3151 South Vaughn Way, Suite 411  
Aurora, Colorado 80014  
(303) 338-0997

Date: May 29, 2001

VERSION OF CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

20. (Amended) The [A] method of claim 1, wherein the [for making multi-component particles including insulin and a biocompatible polymer for sustained insulin delivery, the method comprising:

contacting a] feed solution includes [including both insulin and] a biocompatible polymer and the insulin-containing particles comprise [with a compressed anti-solvent fluid to precipitate] multi-component particles including the insulin and the biocompatible polymer[, the feed solution including a cosolvent system with at least a first organic solvent and a second organic solvent that are mutually soluble; and

separating the multi-component particles from the anti-solvent fluid].

30. (Amended) The method of claim 29, wherein the acid comprises an [and] inorganic acid.

48. The method of claim 20 [19], wherein the biocompatible polymer includes a poly(lactic acid).